# G2A

# Increase Focus

# FDA 483

# QSIT VALIDATION WORKSHEET

| Item # | Goal/Outcome | |
|---|---|---|
| G2A (Activity 1) | Increase the focus of FDA 483 listed Quality System deficiencies on key elements of the major subsystems of the Quality System with linkages to the remaining subsystems. | |
| **Term**[1] | **Type of activity** (test or analysis) | **Parameter**(s) to be measured |
| Short | Test | 1. Comparison of FDA 483 items to the steps in the QSIT Handbook flowcharts. 2. Subsystems associated with QSIT FDA 483 items vs non-QSIT FDA 483 items. 3. QSIT OAI rate vs non-QSIT OAI rate. |
| **Scope and nature** of the process to be followed.[2] | During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections.<br><br>Beginning the week of 1/11/99, the FDA 483s for the QSIT Study inspections will be reviewed by C. Tylka, HFZ-320. The QS regulation FDA 483 items will be compared to the steps of the flowcharts in the QSIT Handbook. The flowchart steps correspond to the key elements of the firm's Quality System that are to be evaluated when performing a QSIT inspection. The results of the reviews will be tabulated and assessed. The match of the FDA 483 items to the flowchart steps will indicate that the QSIT FDA 483 items focused on the key elements of the major subsystems.<br><br>The subsystems associated with the 10 most prevalent QSIT FDA 483 items will also be compared to the subsystems associated with the 10 most prevalent QS regulation FDA 483 items from non-QSIT inspections conducted during the period 6/97-6/98. Design Control deficiencies during this period were listed as Areas of Needed Improvement. However, they were tracked in the CDRH database and will be included in this evaluation. The FDA 483 items from non-QSIT inspections will be identified from the FDA483 database maintained by HFZ-305. The results will be tabulated and assessed. The correspondence of FDA 483 items to the 4 major subsystems (Management, Design, CAPA and PAPC) will indicate that the FDA 483 focused on the major subsystems of the regulation. An increase in the correspondence of QSIT FDA 483 items vs non-QSIT FDA 483 items will indicate an increase in focus on the major subsystems.<br><br>The OAI rate associated with QSIT inspections, based on classifications by QSIT trained Compliance Officers using the QSIT Draft Part V of the Compliance Program 7382.830, will be compared to non-QSIT inspections performed during FY 98. The OAI rate for FY 98 will be obtained from HFZ-305. QSIT was designed to focu the inspection on the assessment of the key elements of the Quality System. FDA 483s resulting from the inspections should also contain items which focus on those key elements. Inspections conducted using QSIT, an approach which focuses on key elements, should yield at least the same or greater violation (OAI) rate as inspections conducted using the non-QSIT approach.<br><br>Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332) | |
| **Acceptance criteria** (if known) | 1. The majority of the FDA 483 items correspond to the steps of the QSIT flowchart.<br>2. There is more of a correspondence of the QSIT FDA 483 items with the major subsystems of the QS regulation then non-QSIT FDA 483 items.<br>3. The OAI rate for QSIT inspections is at least equal to or greater then that of non-QSIT inspections. | |
| Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)** | | This activity provides a direct and objective measurement on whether QSIT FDA 483s focus on the key Quality System elements. It indirectly compares the focus of QSIT FDA 483s to non-QSIT FDA 483s. |
| Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome. | | This pre-deployment activity will demonstrate if the QSIT FDA 483s were focused. It will indirectly measure whether or not the FDA 483 focus has increased. |

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

# QSIT VALIDATION ACTIVITY REPORT

| Item # | Goal/Outcome | |
|---|---|---|
| G2A | Increase the focus of FDA 483 listed Quality System deficiencies on key elements of the major subsystems of the Quality System with linkages to the remaining subsystems. | |
| **Activity #** | **Type of activity** (test or analysis) | **Parameter(s)** to be measured |
| 1 | Test | 1. Comparison of FDA 483 items to the steps in the QSIT Handbook flowcharts. 2, Subsystems associated with QSIT FDA 483 items vs non-QSIT FDA 483 items. 3. QSIT OAI rate vs non-QSIT QAI rate. |
| **Acceptance Criteria** | 1. The majority of the FDA-483 items correspond to the steps of the QSIT flowchart.<br>2. There is more of a correspondence of the QSIT FDA 483 items with the major subsystems of the QS regulation then non-QSIT FDA 483 items.<br>3. The OAI rate for QSIT inspections is at least equal to or greater then that of non-QSIT inspections. | |
| **Summary of Results** | The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT.<br><br>A total of 42 QSIT inspections were conducted during the Study. A total of 28 FDA 483s containing a total of 200 items were issued during those inspections.<br><br>The FDA 483s were reviewed by HFZ-320 and the individual FDA 483 items were compared to the steps of the flowcharts in the QSIT Handbook. The flowchart steps correspond to the key elements of the major subsystems of the Quality System<br><br>A tabulation of the results is attached.<br><br>Part 1<br>A total of 178 of the 200 FDA 483 items were found to match the QSIT Handbook flowchart steps. Of the remaining 22 items, 10 were directly linked to CAPA and PAPC flowchart steps. The remaining 12 items appear to be linked to PAPC flowchart steps.<br><br>This activity has demonstrated that the QSIT FDA 483 items focused on the key elements of the major subsystems of the Quality System.<br><br>Part 2<br>A comparison of the 10 most prevalent FDA 483 items from QSIT and non-QSIT inspections found the QSIT items to correspond more with the major subsystems as follows:<br><br>QSIT Inspections: Management 40%, CAPA 30%, PAPC 20%, and D&R 10%<br>Non-QSIT Inspections: CAPA 50%, PAPC 30%, and D&R 20%<br><br>This increase in the correspondence indicates an increase in focus on the major subsystems.<br><br>Part 3<br>A total of 9 QSIT inspections were classified OAI, using the QSIT Draft Part V of the Compliance Program 7382.830, by QSIT trained Compliance Officers. The OAI rate for QSIT inspections classified in this manner was 21%. The OAI rate for FY 98 was 16%. This equates to an increase in the OAI rate of 31%. | |
| | The findings do [X] do not [ ] meet the acceptance criteria for this activity. | |
| **Additional Comments** | | |
| **Activity Champion(s)** | Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332) | |

Attachment 1 - Item # G2A (Activity 1)

Part 1

FDA483 Review Results
(QS Regulation Deficiencies)

| | CODE | 1 A 1 | 1 A 2 | 1 A 3 | 1 A 4 | 1 B 1 | 1 C 1 | 1 C 3 | 1 C 4 | 1 D 1 | 1 D 2 | 1 D 3 | 1 D 4 | 2 A 1 | 2 B 1 | 2 B 2 | 2 C 4 | 2 D 2 | 2 D 3 | 2 D 4 | 3 A 1 | 3 A 4 | 3 B 1 | 3 B 2 | 3 B 3 | 3 B 4 | 3 C 2 | 3 C 3 | 3 D 3 | TOTAL |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MGMT | 1 | | | | 3 | | 1 | | | 1 | | | | 1 | | | | | | | | 1 | 3 | | 1 | | 1 | | | 12 |
| | 2 | | | | | | | | | | 2 | 1 | | | | | | | | | | | | | | | | | 1 | 4 |
| | 3a | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 3b | | | | | 1 | | 1 | | | 2 | | | | | | | | | | | 1 | 2 | | | 1 | | | | 8 |
| | 4a | 1 | | | 1 | | | | | | | | | | | | | | | | | | 1 | | | | 1 | 1 | | 5 |
| | 4b | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 5 | 2 | | | | 1 | | 2 | | 1 | 1 | 2 | | 1 | | | | | | | | | | | | | 1 | 1 | | 12 |
| | 6 | 2 | 1 | | 1 | 1 | | 2 | | 2 | 2 | 1 | | | | | 1 | | | | | | 1 | 1 | | 1 | | | | 16 |
| DESIGN | 1 | | | | | | | 1 | | | | | | | | | | | | | | | | | | | | | | 1 |
| | 2 | | | | 1 | | | | | 1 | 1 | | | | | | | | | | | | | | | | | | | 3 |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 5 | | | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| | 6 | | | | | | 1 | | | | | | | | | | | | | | | | | | 1 | | | | | 2 |
| | 7 | | | 1 | | | | | 1 | | | | | | | | | | | | | | | | | | | | | 2 |
| | 8 | | | | | | | | | | 2 | | | | | | | | | | | | | | | | | | | 2 |
| | 9 | | | | | | 1 | | | | | | | | | | | | | | | | | | | | | | | 1 |
| | 10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 11 | | | | | | | | 1 | | 1 | | | | | | | | | | | | | | | | | | | 2 |
| | 12 | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | | | 1 |
| | 13 | 1 | | 1 | | | 2 | | | | | | | | | | | | | | 2 | | | | | | | 1 | | 7 |
| | 14 | | 1 | | | | | | | | | | | | 1 | | | | | | | | | 1 | 1 | | | | | 4 |
| | 15 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |

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| | CODE | 1 A 1 | 1 A 2 | 1 A 3 | 1 A 4 | 1 B 1 | 1 C 1 | 1 C 3 | 1 C 4 | 1 D 1 | 1 D 2 | 1 D 3 | 1 D 4 | 2 A 1 | 2 B 1 | 2 B 2 | 2 C 4 | 2 D 2 | 2 D 3 | 2 D 4 | 3 A 1 | 3 A 4 | 3 B 1 | 3 B 2 | 3 B 3 | 3 B 4 | 3 C 2 | 3 C 3 | 3 D 3 | TOTAL |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CAPA | 1 | 1 | | | 3 | | 1 | | | 1 | | | | 1 | | 1 | | | | | | | | | 1 | | 1 | 2 | 12 |
| | 2 | | | 2 | | | 1 | 2 | | | 1 | | | | | 2 | | | 1 | | 1 | | 1 | | | | | | | 11 |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 4 | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | 1 |
| | 5 | | | | | | 1 | | | | | | | | | | | | | | | | | | 1 | | | | | 2 |
| | 6 | | | | | | | 3 | | | 1 | | | | | 2 | | | 2 | | 1 | | | | | | | | | 9 |
| | 7 | | | 1 | | | | | 1 | | | | | | | | 1 | | | | | 1 | | | 3 | | | | | 7 |
| | 8 | | 2 | | | | | 1 | | | | | | | | | | | | | | | | | | | | | | 3 |
| | 9 | 1 | | | | | | 1 | | | | | | | 2 | | | | | | | | | | | | | | | 4 |
| | 10 | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | | | 1 |
| PAPC | 1a | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 1b | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| | 2 | | | | 1 | 2 | 1 | 1 | 4 | 1 | 1 | | 2 | 1 | | | | 1 | 2 | | 3 | 1 | 1 | 3 | 1 | 1 | | 1 | 1 | 29 |
| | 3a | | | | | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| | 3b | 1 | | | | | | 1 | | 1 | | | | | | | | | | | 3 | | 1 | 1 | | | | | | 8 |
| | 4 | | | | | | | | 1 | | | | | | | | | | | | 1 | 1 | | | | | | | | 3 |
| | 5 | | | | | | | | | | | | | | | | | | 1 | | | 1 | | | | | | | | 2 |
| | 6 | | | | | | | | | | | | | | | | | | | 1 | | | | | | 1 | | | | 2 |
| Other | | | 1[1] | | | | 4[1] | | | 1[1] | 1 | 5 | | 1 | | | | | | | 2[1] | 3 | | | 2[2] | 1 | | | | 22 |
| Total[2] | | 9 | 5 | 6 | 10 | 6 | 13 | 15 | 8 | 9 | 15 | 9 | 2 | 5 | 3 | 5 | 2 | 1 | 6 | 2 | 15 | 9 | 10 | 6 | 6 | 11 | 3 | 5 | 4 | 200 |

[1] Linkage between PAPC and D&R

[2] Linkage between CAPA and D&R

Attachment 1 Item # G2A (Activity 1)

Part 2

Review of the QS Regulation FDA 483 items from QSIT and non-QSIT inspections found the 10 most prevalent items to be associated with the following subsystems:

QSIT Inspections
Management (40%)
CAPA (30%)
PAPC (20%)
Documents & Records (10%)

Non-QSIT inspections
CAPA (50%)
PAPC (30%)
Documents & Records (20%)

Part 3

The following QSIT inspections were classified OAI, using the QSIT Draft Part V of the Compliance Program, by the QSIT trained Compliance Officers who participated in the Study:

| | | |
|---|---|---|
| 1. 1A1 | 4. 1C4 | 7. 1D3 |
| 2. 1A4 | 5. 1D1 | 8. 2D3 |
| 3. 1C3 | 6. 1D2 | 9. 3B4 |

There were 42 inspections conducted during the Study. The QAI rate for QSIT inspections using the QSIT Draft Part V was 21%.

The OAI rate for FY 98 was 16%.